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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,346	11/13/2001	Cynthia A. Edwards	54600.8175.US03	1221
22918	7590	11/05/2003	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/993,346		EDWARDS ET AL.	
	Examiner		Art Unit	
	David A. Lambertson		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 23-33) in the response filed August 4, 2003 is acknowledged.

Acknowledgement is also made of a preliminary amendment filed January 16, 2003 that was inadvertently not considered with respect to the Restriction/Election requirement mailed June 30, 2003. The amendment was not matched with the file wrapper until after the mailing of the Restriction/Election requirement, but has now been entered and considered (see the attached Interview Summary).

Claim 34 is now pending and under consideration in the instant application. Claims 1-33 were cancelled in the preliminary amendment filed January 16, 2003.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/354,947, filed July 15, 1999, as well as a number of additional applications. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121

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and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

It is noted that Applicant has included an amendment to the specification including such a reference to the priority applications, filed January 16, 2003. However, the instant application was filed on November 13, 2001, which is subsequent to the November 29, 2000 date requiring that an amendment to correct a claim for priority in the first line of the specification be filed during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. Since the amendment was filed in excess of four months from the filing of the instant specification and in excess of sixteen months from the filing of the priority document, and the amendment was not accompanied by a grantable petition to accept an unintentionally delayed claim for priority, the amendment is improper and has not been entered for purposes of claiming priority. Until such a petition is received and granted by the Office, a priority claim to the indicated applications is considered waived, and no determination of priority has been made regarding these applications. As such, the priority date for the instant application is granted only so far as the filing date, November 13, 2001.

Information Disclosure Statement

The information disclosure statements filed June 27, 2002 and April 8, 2003 have been considered, and a signed and initialed copy of the form PTO-1449s have been attached to this Office Action.

Specification

The disclosure is objected to because of the following informalities: a preliminary amendment was filed to enter a priority claim into the first line of the specification. This preliminary amendment is improper for the reasons set forth above, and is not considered with respect to the granting of priority. Applicant must either cancel the amendment to the priority claim, or perfect the priority claim as indicated above.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Edwards *et al.* (US 5,693,463; see entire document; henceforth Edwards '463; US 5,578,444; US 5,726,014; US 6,010,849; US 5,738,990; US 5,744,131). It is noted that this rejection is presented in light

of the denial of priority indicated above. In the interest of brevity, the rejection is presented only in the context of Edwards '463 because the explicit description of each rejection would be essentially the same as that indicated above for Edwards '463, with minor alterations in the specific location of each teaching within the reference.

Edwards '463 teaches a method where small molecules that are capable of binding to a "test sequence" in a duplex DNA are introduced into a test system composed of a DNA binding protein known to bind a "screening sequence" in a duplex DNA, and a duplex DNA molecule comprising both a "test sequence" and a "screening sequence" adjacent to one another (see for example column 4, line 59 to column 5, line 4). Upon the introduction of the small molecule into the test system, the ability of the DNA binding protein to remain bound to the duplex DNA molecule is measured as a consequence of the small molecule being added (see for example column 5, lines 5-10); in effect, the small molecule is altering the binding characteristics of the DNA binding protein by decreasing its ability to bind its cognate sequence. Thus, Edwards '463 teaches all of the elements of the claimed invention.

Claim 34 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Edwards *et al.* (US 5,306,619; IDS reference; see entire document; henceforth Edwards '619). It is noted that this rejection is presented in light of the denial of priority indicated above.

Edwards '619 teaches a method where small molecules that are capable of binding to a "test sequence" in a duplex DNA are introduced into a test system composed of a DNA binding protein known to bind a "screening sequence" in a duplex DNA, and a duplex DNA molecule comprising both a "test sequence" and a "screening sequence" adjacent to one another (see for

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example column 2, line 58 to column 3, line 13). Upon the introduction of the small molecule into the test system, the ability of the DNA binding protein to remain bound to the duplex DNA molecule is measured as a consequence of the small molecule being added (see for example column 5, lines 7-13); in effect, the small molecule is altering the binding characteristics of the DNA binding protein by decreasing its ability to bind its cognate sequence. Thus, Edwards '619 teaches all of the elements of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 34 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,578,444 (henceforth the '444 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is a genus claim that is anticipated by the species claim of the '444 patent. Specifically, claim 1 of the '444 patent is directed to a method that is identical to the instantly claimed method, with the exception that claim 1 of the '444 patent adds the limitation where the test sequence and the screening sequence of the DNA duplex molecule are

not overlapping by more than four base pairs. This is a species of the claimed genus of the instant application because this limitation falls within the broader scope of a method using a DNA duplex molecule where the test sequence and screening sequence are adjacent. As such, if one were to practice a method using a DNA duplex where the test sequence and screening sequence were separated by 1 base pair, the method would read on both the claim of the instant invention and claim 1 of the '444 patent. Therefore, the claims are subject to rejection under the judicially created doctrine of Obviousness Double Patenting.

Allowable Subject Matter


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU1636


JAMES KETTER
PRIMARY EXAMINER